

Interamerican College of Physicians & Surgeons

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May 18, 2000

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Nobel Prize in Medicine (1984)

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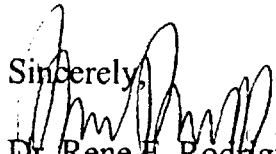
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Food and Drug Administration
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Rockville, MD 20852

To Whom It May Concern:

The Interamerican College of Physicians and Surgeons requests that the attached statement be submitted into the public record for the public hearing on Over-the-Counter Drug Products on June 28-29 in response to the FDA's request for comments on the criteria the agency should consider in rendering decisions on specific classes of products that are not currently marketed OTC that should be available OTC, such as for cholesterol-lowering drugs.

Sincerely,


Dr. Rene F. Rodriguez
President

OON-1256

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Statement of the Interamerican College of Physicians and Surgeons in Support of Low-Dose Statin Drugs as an Over-the-Counter Medication

In response to the FDA's invitation for public comment about the agency's approach to regulating over-the-counter (OTC) drug products -- including whether there are products that are not currently available OTC that should be available OTC -- the Interamerican College of Physicians and Surgeons (ICPS) is submitting this statement in support of approval of low-dose statin drugs as an over-the-counter (OTC) medication for people with mild to moderately elevated cholesterol.

As the national organization representing over 39,000 health professionals in the Hispanic community, ICPS' primary goal is to strengthen health service delivery to the Hispanic community. We believe that offering HMG CoA reductase inhibitors over-the counter is an important step in that direction by providing greater access to a clinically proven therapy for treating elevated cholesterol.

Today, cardiovascular disease remains the leading cause of death for Hispanics in the United States, representing 26.9 percent and 33.3 percent of total deaths for males and females respectively in 1996. Moreover, Hispanics, who are less likely to have access to health insurance and adequate preventive medical care, suffer a greater incidence of cardiovascular disease than the general population. For example, 39 percent of Mexican American men and 38 percent of Mexican American women age 20 years old and older have LDL-C levels greater than 130 mg/dL.

The problem of elevated cholesterol requires additional treatment options to reinforce ongoing efforts and we believe that offering statins over-the-counter would provide patients with greater access to a proven therapy for treating elevated cholesterol. Numerous randomized, placebo controlled clinical trials have shown that statins dramatically reduce the risk of heart attack even for patients who show no signs of heart disease. Statin products that have a long history of safe use and minimal side effects could be used safely and responsibly in an OTC setting. For people who continue to struggle with elevated cholesterol levels despite healthy diets and exercise, OTC statins would provide a new safe and effective treatment option approved by the FDA.

Today's consumers want and deserve statin products over-the-counter. There is an increasing trend in self-care among consumers. Functional foods, dietary supplements and other alternative therapies claiming to lower cholesterol are already used extensively even though the jury is still out on them - OTC statins would provide a clinically proven alternative approved by the FDA. In addition, OTC product advertising and educational information would increase awareness about this serious public health threat.

The Interamerican College of Physicians and Surgeons believes that making statins available over-the counter is a significant step in the battle against heart disease.